



3410-34-P

DEPARTMENT OF AGRICULTURE

Office of the Secretary

[Docket No. APHIS-2012-0039]

Privacy Act Systems of Records; LabWare Laboratory Information Management System

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of a proposed new system of records.

SUMMARY: The Animal and Plant Health Inspection Service proposes to add a system of records to its inventory of records systems subject to the Privacy Act of 1974, as amended. The system of records is the LabWare Laboratory Information Management System, USDA-APHIS-19. This notice is necessary to meet the requirements of the Privacy Act to publish in the Federal Register notice of the existence and character of record systems maintained by the agency.

DATES:

Effective Date: This system will be adopted without further notice on [Insert date 40 days after date of publication in the Federal Register] unless modified to respond to comments received from the public and published in a subsequent notice.

Comment Date: Comments must be received in writing on or before [Insert date 30 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to

<http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0039-0001>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2012-0039, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0039> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Elizabeth A. Lautner, NVSL LabWare LIMS Owner, NVSL, APHIS, 1920 Dayton Avenue, Ames, IA 50010; (515) 337-7301.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Privacy Act of 1974, as amended (5 U.S.C. 552a), requires agencies to publish in the Federal Register notice of new or revised systems of records maintained by the agency. A system of records is a group of any records under the control of any agency, from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to an individual.

The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) is proposing to add a new system of records, entitled LabWare Laboratory Information Management System (LabWare LIMS), to maintain a record of

activities conducted by the agency pursuant to its mission and responsibilities authorized by the Animal Health Protection Act (7 U.S.C. 8301 et seq.).

LabWare LIMS is used to track and save results of diagnostic testing performed by or under the auspices of APHIS' National Veterinary Services Laboratories (NVSL).

Diagnostic testing provides official test results for animal imports, exports, and interstate movements, and for certifying the disease status of herds and States or zones. Diagnostic testing is also done in connection with suspected foreign animal disease investigations and domestic control and eradication programs. Records in the system provide current and historical data used for detecting animal diseases, conducting emergency responses, conducting and evaluating animal disease control measures, performing epidemiological investigations, and forecasting possible animal disease occurrences and outbreaks.

The LabWare LIMS holds information related to submitters and owners of samples submitted for diagnostic testing, as well as sample specific information, testing data, and information on reagents used for tests.

Information about submitters and owners of diagnostic samples includes some or all of the following: Name, shipping address, invoice address, telephone number, e-mail address, and National Finance Center account number or credit card number (last four digits only). This information is required in order to identify diagnostic samples and track and save test results, report test results, and bill for services.

Information about submitters and owners of diagnostic samples is from submission forms that accompany laboratory specimens sent to the NVSL for diagnostic testing. The NVSL receives approximately 50,000 submissions annually from State and

private veterinary diagnostic laboratories, as well as private veterinary practitioners, Federal meat inspectors, Federal field veterinarians, and others. In addition, the NVSL receives laboratory samples from other countries related to imports and for cases where other countries request diagnostic assistance.

Additionally, the system contains information about APHIS employees who enter data into the system, including some or all of the following: Name, job title, business telephone number, business e-mail address, supervisor's name, organizational group to which employee belongs within the NVSL and APHIS' Center for Veterinary Biologics, and training and proficiency records related to diagnostic testing. Employee information contained in the system creates data for APHIS' User Fees System application.

APHIS routinely shares records concerning diagnostic test results with the submitting veterinarian and State veterinarians of the submitter's State, animal owner's State, and animal's location State. They receive a test report with the data submitted and the results of the testing. The original submission form may also be included with the test report.

Other routine uses of records include releases related to litigation or investigations of violations of law. A complete listing of the routine uses of records maintained in this system is included in the document published with this notice.

#### Report on a New System of Records

A report on the new system of records, required by 5 U.S.C. 552a(r), as implemented by OMB Circular A-130, was sent to the Chairman, Committee on Homeland Security and

Governmental Affairs, United States Senate; the Chairman, Committee on Oversight and Government Reform, House of Representatives; and the Administrator, Office of Information and Regulatory Affairs, OMB.

Thomas J. Vilsack,  
Secretary.

System name:

LabWare Laboratory Information Management System (LabWare LIMS), USDA-APHIS–19.

Security classification:

None.

System location:

The master data for the LabWare LIMS is stored and maintained on USDA-owned servers physically located in the secure USDA-owned facility, National Centers for Animal Health in Ames, IA. A backup site for the data is located in USDA offices in Ft. Collins, CO. Paper files are maintained by USDA's National Veterinary Services Laboratories (NVSL) at Ames, IA, and Plum Island, NY.

Categories of individuals covered by the system:

Submitters and owners of animal diagnostic samples received by the NVSL, and USDA employees who enter data into the LabWare LIMS from laboratory records or other paperwork provided by sample submitters.

Categories of records in the system:

The LabWare LIMS will collect some or all of the following information about submitters and owners of diagnostic samples: Name, shipping address, invoice address, telephone number, e-mail address, and National Finance Center account number or credit card number (last four digits only). The LabWare LIMS will collect some or all of the following information about USDA employees who enter data into the system: Name, job title, business telephone number, business e-mail address, supervisor's name,

organizational group to which employee belongs within the NVSL and APHIS' Center for Veterinary Biologics, and diagnostic testing related training and proficiency records.

Authority for maintenance of the system:

The Animal Health Protection Act (7 U.S.C. 8301 et seq.)

Purpose(s):

The LabWare LIMS is a laboratory information system that tracks and saves test results on animal diagnostic samples received at the NVSL.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, records maintained in the system may be disclosed outside USDA as follows:

(1) To the submitting veterinarian and State veterinarians of the submitter State, owner State, and animal location State to provide test results;

(2) To the appropriate agency, whether Federal, State, local, or foreign, charged with responsibility of investigating or prosecuting a violation of law or of enforcing, implementing, or complying with a statute, rule, regulation, or order issued pursuant thereto, of any record within this system when information available indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and either arising by general statute or particular program statute, or by rule, regulation, or court order issued pursuant thereto;

(3) To the Department of Justice when: (a) the agency, or any component thereof; or (b) any employee of the agency in his or her official capacity; or (c) any

employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee; or (d) the United States, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice is deemed by the agency to be relevant and necessary to the litigation; provided, however, that in each case, the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected;

(4) For use in a proceeding before a court or adjudicative body before which the agency is authorized to appear, when: (a) the agency, or any component thereof; or (b) any employee of the agency in his or her official capacity; or (c) any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or (d) the United States, is a party to litigation or has an interest in such litigation, and the agency determines that use of such records is relevant and necessary to the litigation; provided, however, that in each case, the agency determines that disclosure of the records to the court is a use of the information contained in the records that is compatible with the purpose for which the records were collected;

(5) To appropriate agencies, entities, and persons when: (a) the agency suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (b) the agency has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, a risk of identity theft or fraud, or a risk of harm to the security or integrity of this system or other systems or programs (whether maintained by the agency or another agency or entity) that rely upon the compromised information; and (c) the disclosure



made to such agencies, entities, and persons is reasonably necessary to assist in connection with the agency's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm;

(6) To the National Archives and Records Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906.

Disclosure to consumer reporting agencies:

None.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage:

The system includes a database and paper records. The master electronic data is stored and maintained on USDA-owned servers physically located in a secure USDA-owned facility. Paper files, consisting of the submission forms for diagnostic samples, are stored in lockable cabinets in laboratory space or administrative offices.

Retrievability:

Data may be retrieved by an accession number, which is a system generated identification number; or by a sample number assigned by the sample submitter; or by a number assigned by NVSL to a submitter; or by a submitter's name.

Safeguards:

Data are kept in a secure environment at USDA-owned facilities. All access to LabWare LIMS is internal to USDA APHIS staff.

All access to the electronic data in the system is controlled by formal authorization. Each employee's supervisor must identify what functional roles an

employee needs in the LabWare LIMS. Once the roles have been identified, the employee must pass a proficiency test and perform tasks associated with that role before he or she is given access to the production system. All access to the system is limited by username/password. Employees must acknowledge a warning banner before logging in. The application limits access to relevant information and prevents access to unauthorized information. Users are trained and are required to formally confirm that they understand value and sensitivity of data in the system. Submitting veterinarians and State veterinarians receive test reports by e-mail and/or through a Lotus Notes-based system that is fed by LabWare LIMS, but they have no direct access to LabWare LIMS.

Electronic and paper records are further protected by security measures in place at both the Ames and Plum Island facilities related to laboratory work conducted there. In Ames, the entire facility is protected by perimeter fencing and monitored by closed circuit cameras. Access to Plum Island is restricted to contracted and monitored ferry service. At both locations, buildings are locked, guarded, and monitored around the clock, and laboratory spaces have additional security measures.

#### Retention and disposal:

Records will be retained indefinitely pending approval of a records retention schedule by the National Archives and Records Administration. Under the schedule submitted for approval, paper records would be retained for a minimum of 3 years, data would be maintained in the system for 25 years, and would be archived at 5-year intervals.

#### System manager(s) and address:

Director, National Veterinary Services Laboratories, 1920 Dayton Avenue, Ames, IA 50010.

Notification procedure:

Any individual may request general information regarding this system of records or information as to whether the system contains records pertaining to him/her from the system manager at the address above. All inquiries pertaining to this system should be in writing, must name the system of records as set forth in the system notice, and must contain the individual's name, telephone number, address, and e-mail address.

Record access procedures:

Any individual may obtain information from a record in the system that pertains to him or her. Requests for hard copies of records should be in writing, and the request must contain the requesting individual's name, address, name of the system of records, timeframe for the records in question, any other pertinent information to help identify the file, and a copy of his/her photo identification containing a current address for verification of identification. All inquiries should be addressed to the Freedom of Information and Privacy Act Staff, Legislative and Public Affairs, APHIS, 4700 River Road Unit 50, Riverdale, MD 20737-1232.

Contesting record procedures:

Any individual may contest information contained within a record in the system that pertains to him/her by submitting a written request to the system manager at the address above. Include the reason for contesting the record and the proposed amendment to the information with supporting documentation to show how the record is inaccurate.

Record source categories:

The sources of information in the system are from submission forms that accompany laboratory specimens sent into the laboratory for diagnostic testing. The NVSL receives submissions from State and private veterinary diagnostic laboratories as well as private veterinary practitioners, Federal meat inspectors, Federal field veterinarians, and others. In addition, the NVSL receives laboratory samples from other countries associated with imports and for cases where diagnostic assistance is requested.

Exemptions claimed for the system:

None.

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